DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 7-16) and the species of CXCL10 in the reply filed on 5/10/2010 is acknowledged. The traversal is on the ground(s) that there is no undue search burden on the examiner (Remarks, p. 1). Applicant's arguments have been fully considered. In light of the fact that the elected Group contains additional steps that are no encompassed by the remaining Group, but the steps of the non-elected group are subsumed within the elected group, the Restriction between Groups I and II is withdrawn. However, the species election is maintained. The traversal as to the species of chemokines poses an excessive undue search burden. The structure and function of the cytokines in the Markush groups of claims 1 and 7 are each independent and distinct, absent an admission from Applicant that they are equivalents. The examiner has found no evidence of record indicating that the recited list of chemokines are equivalents. Accordingly, they are treated as distinct alternative embodiments; each of which requires a separate search in the patent and non-patent literature. Applicant is reminded that if the elected species is found to be free of the prior art, the search of other species will proceed in a step-wise manner.

Formal Matters

2. New claims 18 and 19 have been added. Claim 16 has been cancelled. Claims 1-15 and 17-19 are pending and under examination as they are drawn to the species of CXCL10.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 10/14/2010 has been considered by the examiner. A signed copy is attached.

Interview Summary

4. An interview summary is attached outlining the numerous phone calls from Applicant's Representative, inquiring about the status of the First Action on the Merits at the request of Applicant. Applicant is on notice regarding any such continued actions. It is not productive for Applicant's Representative to make or the examiner to respond to such multiple repetitive requests every other week. The examiner is well aware of the age of the instant application. The file wrapper history clearly shows that the application was abandoned and revived. Applicant's desire for a quick action from the Office is understood, but continually harassing the examiner will not expedite examination. On 11/2/2010,

Applicant's representative was clearly and unambiguously informed that the FAOM was expected to be completed in mid-December and that the examiner would, out of courtesy, contact Applicant's representative when the FAOM was completed. There was no need for the multiple phone calls by Applicant's Representative regarding the status of the examination of the instant application. Applicant is referred to the MPEP for the official time lines delineated for examination.

Claim Rejections - 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-15, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there are no correlation steps relating the exposure step (claim 7), the identification steps (claims 7 and 12), and the administration steps (claims 7 and 12). The claims, as written, lack steps correlating the exposure and identification steps with the administration steps for a method of treatment. Without such correlation steps, the exposure and identification steps are superfluous to the administration step. Claims 8-11, 13-15, 18, and 19 are rejected as depending from rejected claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 5-10, 12-14, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Karin, US 20030166589 (4 September 2003, benefit to 5 June 2001)

Karin teaches methods of inhibiting inflammation comprising administering an anti-IP-10 (also known as CXCL10 and interferon gamma-inducible protein 10) antibody in a pharmaceutically

acceptable carrier, including a liquid, for human or veterinary use (claim 42, 43, and 50-52; paragraphs 1, 16, 18, 120, 121, 124-126, 133-134, 145, 191) (compare instant claims 1-3, 7, 10, and 17-19). Humans and other mammals are taught at paragraph 68 and are included in the definition of "subject" (compare instant claim 3). Human, humanized, and chimeric antibodies to CXCL10 are taught at paragraph 91-93 (compare instant claims5). Administration directly into an inflamed tissue, parenteral, and systemic administration are taught at paragraphs 123, 131, 132-133 (compare instant claims 6, 8, 9, 13, and 14). Exposure of tissues to anti-CXCL10 antibodies and identifying the level of chemokine based on binding of the antibodies is taught at paragraph 191 (especially the latter half of the paragraph) (compare instant claim 7). Identification of CXCL10 using PCR on tissue samples is taught at paragraph 160 (compare instant claims 12 and 19).

9. Claims 1-11, 18, and 19 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Lane, WO 02/015932 (28 February 2002, benefit to 18 August 2000).

Lane teaches administration of anti-IP-10 (also known as CXCL10) antibodies to inhibit inflammation and treat inflammatory disorders in mammals and humans (abstract; p. 9, lines 25-29; p. 17, second paragraph; p. 26, third paragraph) (compare instant claims 1, 3, 7, 18, and 19). Human, chimeric, and humanized antibodies are taught at p. 24, first paragraph; page 26, 3rd paragraph to p. 34) (compare instant claim 5). Administration by systemic, parenteral, and direct to tissue is taught at p. 38, third paragraph and p. 39, first paragraph (compare instant claims 6, 8, and 9). Administration in a liquid is taught at p. 39, second paragraph to page 41 (compare instant claims 2 and 10). Antibodies incorporated into biodegradable polymers (solid supports) are taught at p. 39, first paragraph (compare instant claims 4 and 11). Exposure and expression level identification assays are taught at p. 35, third paragraph; and Example 3) (compare instant claim 7).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karin, US 20030166589 (benefit to 5 June 2001) and Lane, WO 02/015932 (28 February 2002, benefit to 18 August 2000).

The examiner finds the following facts:

a. Karin teaches methods of inhibiting inflammation comprising administering an anti-IP-10 (also known as CXCL10 and interferon gamma-inducible protein 10) antibody in a pharmaceutically acceptable carrier, including a liquid, for human or veterinary use (claim 42, 43, and 50-52; paragraphs 1, 16, 18, 120, 121, 124-126, 133-134, 145, 191) (compare instant claims 1-3, 7, 10, and 17-19). Humans and other mammals are taught at paragraph 68 and are included in the definition of "subject" (compare instant claim 3). Human, humanized, and chimeric antibodies to CXCL10 are taught at paragraph 91-93 (compare instant claims5). Administration directly into an inflamed tissue, parenteral, and systemic administration are taught at paragraphs 123, 131, 132-133 (compare instant claims 6, 8, 9, 13, and 14). Exposure of tissues to anti-CXCL10 antibodies and identifying the level of chemokine based on binding of the antibodies is taught at paragraph 191 (especially the latter half of the paragraph) (compare instant claim 7). Identification of CXCL10 using PCR on tissue samples is taught at paragraph 160 (compare instant claims 12 and 19).

b. Karin does not teach carriers on solid supports.

c. Lane teaches administration of anti-IP-10 (also known as CXCL10) antibodies to inhibit inflammation and treat inflammatory disorders in mammals and humans (abstract; p. 9, lines 25-29; p. 17, second paragraph; p. 26, third paragraph) (compare instant claims 1, 3, 7, 18, and 19). Human, chimeric, and humanized antibodies are taught at p. 24, first paragraph; page 26, 3rd paragraph to p. 34) (compare instant claim 5). Administration by systemic, parenteral, and direct to tissue is taught at p. 38, third paragraph and p. 39, first paragraph (compare instant claims 6, 8, and 9). Administration in a liquid is taught at p. 39, second paragraph to page 41 (compare instant claims 2 and 10). Antibodies incorporated into biodegradable polymers (solid supports) are taught at p. 39, first paragraph (compare instant claims 4 and 11). Exposure and expression level identification assays are taught at p. 35, third paragraph; and Example 3) (compare instant claim 7).

d. One of ordinary skill in the art would have reasonably known that antibodies could be incorporated on or in carriers that are solid supports, such as the biodegradable polymers of Lane.

e. Karin and Lane teach methods of treatment using anti-CXCL10 (also known as IP-10) antibodies for the same purpose.

f. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.).

In view of the facts recited above, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. The prior art teaches all of the limitations of the claimed invention. The person of ordinary skill in the art could have combined the elements as claimed by known methods to produce a method of treatment comprising an antibody attached to a solid support, based on the express

teachings of Lane. One of ordinary skill in the art would have recognized that the results of the combination of a method of treatment comprising an antibody attached to a solid support would have yielded nothing more than predictable results to one of ordinary skill in the art at the time the invention was made. This is demonstrated by the fact that both Karin and Lane teach methods of treating inflammatory disorders by administering anti-CXCL10 (IP-10) and Lane teaches treatment comprising administering the antibodies with carriers that are solid supports

Conclusion

14. The prior art made of record and not presently relied upon is considered pertinent to applicant's disclosure:

Angostini et al., (Am J Path. May 2001:158(5):1703-1711) teach methods of treating pulmonary immunoinflammation comprising administering anti-CXCL10 antagonists. Identification and expression levels of CXCL10 in humans is taught at p. 1706, column 2 and Figure 4 from transbronchial biopsy using anti-CXCL10 antibodies. Therapeutic implications, including administration of anti-CXCL10 antagonists are taught at p. 1709, column 2, first paragraph, and p. 1710, second paragraph.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647